

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/002893

International filing date (day/month/year)
02.02.2004

Priority date (day/month/year)
31.01.2003

International Patent Classification (IPC) or both national classification and IPC
A61B17/22, A61B17/32

Applicant
HYDROCISION INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Schießl, W

Telephone No. +49 89 2399-7436



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/002893

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/002893

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/002893

Box No. III – Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 32, 34-37, 46-58, 60, 62-70

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 32, 34-37, 46-58, 60, 62-70 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/002893

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-4,6,9,15-21,26,27,30-70,86,89,111-113

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-4,6,9,15-21,26,27,30,31,33,38-45,59,61,86,89,111-113
Inventive step (IS)	Yes: Claims	
	No: Claims	1-4,6,9,15-21,26,27,30,31,33,38-45,59,61,86,89,111-113
Industrial applicability (IA)	Yes: Claims	
	No: Claims	1-4,6,9,15-21,26,27,30,31,33,38-45,59,61,86,89,111-113

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/002893

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Section III

The subject-matter of various searched claims is known from the prior art (cf. V, 2 below). The different combinations of features recited in the remaining searched dependent claims 32, 34-37, 46-58, 60, and 62-70 do not clearly define the matter for which protection is sought (Article 6 PCT) and thus do not allow to identify "**the** claimed invention" in the sense of Article 33.1 PCT, on which a further opinion should be based.

Section IV

- 1 The International Examining Authority considers that the present International Application does not comply with the requirement of unity of invention (Rule 13 PCT):
 - 1.1 The subject-matter of claims 1, 2, 6, 9, 15-21, 26, 27, 86, 89, 111, and 113 is known from D1 and thus not new in the sense of Article 33(2) PCT (see V, 2 below).
 - 1.2 Accordingly, potential special features, representing a possible contribution over the prior art, of the claims refer to:

Claims 3, 4, 30-70, 112:

An instrument with a holder having a recessed well

Claims 5, 71-85, 115-138:

An instrument with a ring-shaped nozzle providing component and a method of fabrication thereof

Claims 7, 10-13, 87, 90-92, 94-104, 114:

An instrument with specific dimensions of the flow path

Claims 8, 14, 22-25, 88, 105-110, 139-141

An instrument including an evacuation lumen opposite the nozzle and a method of assembling thereof

Claims 28, 29:

A kit including the instrument and instructions

Claims 93:

An instrument with a nozzle formed by electrodeposition of metal

The subject-matter of these groups of claims is not so linked as to form a single inventive concept (Rule 13.1 PCT), as there no technical relationship between the corresponding groups of special technical features is apparent.

Section V

- 1 Reference is made to the following documents (D) cited in the International Search Report:

D1: US-A-6 135 977 (DRASLER WILLIAM J ET AL) 24 October 2000 (2000-10-24)

D2: US-A-5 135 482 (NERACHER ARNOLD) 4 August 1992 (1992-08-04)

- 2 Novelty (Article 33(2) PCT)

- 2.1 The subject-matter of independent claims 1 and 111 is not new, since document D1 (col. 5, l. 44 to col. 6, l. 26; col. 9, ll. 38-48; fig. 27) discloses a surgical instrument comprising: a nozzle assembly comprising a nozzle-providing component (124) that is shaped to form a liquid jet (122); and a pressure lumen (112) configured and positioned to convey a flow of liquid to the nozzle assembly; wherein the nozzle assembly comprises a holder (168, 170) that is configured to retain and position the nozzle-providing component, and wherein the nozzle-providing component comprises a liquid flow passage having a diameter that continuously decreases along at least a portion of a liquid flow path through the liquid flow passage (fig. 27).

- 2.2 D1 also anticipates a surgical instrument according to independent claims 86 and 113 (in that nozzle 124 is considered to be optically smooth).

2.3 D2 shows a surgical instrument and methods as recited in independent claims 1, 30, 59, 86 and 112 (figs. 6-8: optically smooth nozzle-providing component 11, holder 25 with distal recessed well).

2.4 Various dependent claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, as they are either known from D1 or D2 (see search report).

Section VII

- 1 Independent apparatus claims should have been drafted in the two-part form in accordance with Rule 6.3(b) PCT.
- 2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.
- 4 The units 'inch' and 'psig' employed in the application are not additionally expressed in terms of the units stipulated by Rule 10.1(a) and (b) PCT.
- 5 An incorporation of documents by reference (p. 2, 25) is not possible in some of the Designated States.